Seat No.: _____ Enrolment No._____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013**

**Subject Code: 910108 Date: 23-12-2013**

**Subject Name: Industrial Pharmacy- I**

**Time: 10.30 am - 01.30 pm Total Marks: 80**

**Instructions:**

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

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|---|---|---|---|
| **Q.1** | (a) | Describe the factors to be considered in selection of location for pharmaceutical factory. | **06** |
| | (b) | Discuss personnel facilities required in pharmaceutical industry. | **05** |
| | (c) | Describe HVAC as utility service in pharmaceutical factory. | **05** |
| **Q.2** | (a) | Describe departmental layout for oral liquid dosage forms. | **06** |
| | (b) | Discuss the important factors for material selection in pharmaceutical plant construction. | **05** |
| | (c) | Enlist the equipments required for semisolid dosage forms. Describe planetary mixer. | **05** |
| **Q.3** | (a) | Discuss the equipments required in manufacturing of oral solid dosage forms as per schedule- M. | **06** |
| | (b) | Write in brief about equipments used in sterile manufacturing. | **05** |
| | (c) | Give a layout of manufacturing area for cosmetics. | **05** |
| **Q.4** | (a) | What is the significance of SOP? Describe the contents of SOP. | **06** |
| | (b) | Describe the preparation of SOP for sterile packaging. | **05** |
| | (c) | What is documentation? Describe Batch Manufacturing Record. | **05** |
| **Q.5** | (a) | Explain validation. Discuss the contents of validation protocol. | **06** |
| | (b) | What is clean in place? Describe the specifications for purchase of equipments. | **05** |
| | (c) | What is the significance of training in pharmaceutical industry? | **05** |
| **Q. 6** | (a) | What is cGMP? Discuss its significance in pharmaceuticals in brief. | **06** |
| | (b) | Write note on sanitation in manufacturing premises. | **05** |
| | (c) | Write about inventory control of raw materials. | **05** |
| **Q.7** | (a) | Discuss the process of vendor selection for raw materials. | **06** |
| | (b) | Describe the documentation required for batch release. | **05** |
| | (c) | Discuss product recall procedure and documentation. | **05** |

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